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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	18

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action	Application No. 09/125,122	Applicant(s) TARRO ET AL.	
	Examiner Bridget E. Bunner	Art Unit 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 May 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b)

1. ☒ A Notice of Appeal was filed on *18 May 2001*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE _____.

3. ☒ Applicant's reply has overcome the following rejection(s): *See Continuation Sheet*.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☒ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Elizabeth C Kemmerer

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *7,9,11,13,15,17,19 and 20*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other:

Continuation of 3. Applicant's reply has overcome the following rejection(s): The objections to the specification and claims 7-8 are withdrawn in view of the newly submitted specification and cancelled claims.

Continuation of 5. does NOT place the application in condition for allowance because:

Claims 7,9,11,13, 15,17,19-20 are rejected under 35 USC 103(a). Applicants argue that claims 7,9,11,13,15, and 17 are method of treatment claims, and therefore, the intended use alpha-interferon for treating viral hepatitis is critical to the claims and patentably distinct (pg 5, Paper No. 17, 18 May 2001). Applicants assert that Cummins (U.S. patent 5,824,300 and WO 88/03411) does not teach the usefulness of oral liquid alpha-interferon in treating viral hepatitis and that Cummins does not teach the liquid alpha-interferon formulation of claim 19 having a concentration of 100-500 IU/ml (pg 6). Further, Applicants state that a critical feature of the claimed invention is that it uses alpha-interferon in liquid form (pg 8). Applicants also argue that Ratajczak et al. employs lozenges of alpha-interferon and fails to appreciate the importance of administering alpha-interferon in liquid rather than solid form. Applicants also submit a 132 Declaration to further the support the benefits of a liquid formulation of alpha-interferon rather than a tablet form.

Applicants arguments have been fully considered but are not found persuasive for the following reasons. Cummins teaches a liquid formulation containing 1-1500 IU of alpha-interferon in a dosage volume of one tablespoon or 0.07-100 IU/ml (U.S. patent 5,824,300; col. 14) This dosage of alpha-interferon overlaps with the concentration range claimed by the Applicants. Cummins also teaches treatment of neoplastic disease, hyperallergenicity, immuno-resistant or immuno-debilitating viral infections and autoimmune disorders characterized by chronic tissue degenerative inflammation with a liquid formulation of alpha-interferon (col. 7-13). It would have been obvious to one skilled in the art at the time the invention was made to administer alpha-interferon to a subject with viral hepatitis because Cummins teaches it would be desirable to do so. Further, Ratajczak et al. teaches the administration of lozenges containing 50 or 100 IU of human lymphoblastoid alpha-interferon for oral delivery in the treatment of hepatitis B infections (pg 239, col 1). It would have been obvious to one skilled in the art at the time the invention was made to prepare an aqueous formulation of alpha-interferon according to Cummins, employing lymphoblastoid interferon as described by Ratajczak et al. in place of the buffy coat leukocyte interferon noted particularly by Cummins, because Ratajczak et al. evidences that lymphoblastoid interferon was readily available at the time of the invention and teaches that it is suitable for the treatment of an exemplary viral disease via delivery to the oropharyngeal mucosae. Furthermore, the declaration under 37 CFR 1.132 filed 18 May 2001 is insufficient to overcome the rejection of claims 7,9,11,13,15,17, and 19-20. The declaration does not show that the objective evidence of nonobviousness is commensurate in scope with the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bridget E. Bunner
Art Unit 1647
12 June 2001